REMARKS

Claims 7-11 and 14-27 are pending. Claims 7-11 and 14-27 have been rejected. Claims 7, 15, 16, and 22, have been amended to further particularly point out and distinctly claim subject matter regarded as the invention. Claims 14 and 27 have been cancelled without prejudice. No new matter has been added.

Judicially-created Double Patenting

Claims 7-11 and 14-27 have been rejected pursuant to the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of prior United States patent No. 6,183,497. Submitted herewith is a Terminal Disclaimer executed by an Officer of Sub-Q Corporation, assignee of all right, title, and interest in both the above-identified patent application and in United States Patent No. 6,183,497. Withdrawal of this rejection is respectfully requested.

The 35 U.S.C. § 102 Rejection – Independent Claim 7

Claim 7 stands rejected under 35 U.S.C. § 102(e) as being allegedly anticipated Chuang et al. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[1]

[1] Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Amended Claim 7 provides for "the absorbable sponge material includes a contrasting agent substantially dispersed throughout said pledget." As stated in the Specification, the "contrasting agent [is] incorporated in the matrix of the sponge. By 'incorporated' is meant that the contrasting agent is substantially dispersed throughout the sponge so that the contrasting material is not simply found on the periphery of the sponge." (Specification, page 7, lines 26-29 and page 8, line 1). Thus, the contrasting material is substantially dispersed throughout the sponge such that the pledget already contains the contrast material prior to hydration and additional liquid contrasting agent is not required to be added.

Chuang do not teach or suggest an absorbable sponge having a "contrasting agent substantially dispersed throughout said pledget." as provided for in claim 7. Rather, Chuang teaches the method of adding or injecting contrast medium separately from the Gelfoam. Furthermore, Chuang teaches loading the Gelfoam into the tip of syringe, and then filling the syringe with contract medium from the back end thereby hydrating the Gelfoam with the contrast medium. (Chuang, page 1, col. 3, lines 3-7). Chuang requires the use of liquid contrast medium since the Gelfoam itself does not contain any contrast medium and thus, do not teach the contrast medium substantially dispersed throughout the Gelfoam as required in claim 7.

Thus, it is respectfully requested that this rejection be withdrawn.

The 35 U.S.C. § 103 Rejection – Independent Claim 22

Claims 8-11 and 14, 15, and 22-27 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Chuang et al. in view of Daniels, US Patent No. 4,708,718, among which claim 22 is an independent claim. This rejection is respectfully traversed.

According to the Manual of Patent Examining Procedure (M.P.E.P.),

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.[2]

Specifically, the Office Action contends:

> "Chuang et al. discloses the claimed invention except for the specific contrasting agent used in the sponge. Daniels teaches water insoluble or water-soluble contrasting agents may be used in an implanted device so that the sponge may be visualized under X-ray (Column 5 lines 48-64). It would have been obvious to one having ordinary skill in the art to use a water-soluble or water insoluble contrasting agent in the method of Chuang et al. in order to observe the sponge using X-rays."

The Applicants respectfully disagree for the reasons set forth below.

Amended Claim 22 provides that the "contrast agent [is] substantially dispersed throughout said absorbable sponge material".

Neither Chuang nor Daniels teach or suggest an absorbable sponge material with a "contrast agent substantially disposed throughout said absorbable sponge material" as provided for in amended claim 22. Rather, Chuang and Daniels teach the method of adding or injecting liquid contrast medium separately from the Gelfoam or to hydrate the Gelfoam. For example, Daniels teaching that the "collagen material may be mixed . . . with a contrasting agent" and the

[2] M.P.E.P § 2143.

contrasting agent is therefore not incorporated into the collagen material as claimed in amended claim 22. (Col. 5, lines 48-49). Thus, there is no reasonable expectation of success.

Additionally, Chuang and Daniels teach the method of adding or injecting liquid contrast medium separately and/or to the Gelfoam. Thus, the prior art references do not teach or suggest all the claim limitations as set forth in amended claim 22.

The 35 U.S.C. § 103 Rejection – Independent Claim 16

Claims 16-18 and 21 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Chuang et al. in view of Rosenblatt, US Patent No. 4,098,728, among which claim 16 is an independent claim. This rejection is respectfully traversed.

The Office Action states "Chuang discloses the claimed invention except for the contrasting agent being preloaded prior to delivery. Rosenblatt teaches that the entire sponge is radiopaque in order to facilitate the determination of the location of the entire sponge (Column 3 lines 10-17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the radiopaque material into the sponge of Chuang in order to allow the whole sponge to be observed."

Claim 16 provides for an "absorbable sponge material [which] includes a contrast agent preloaded therein prior to hydration".

A. There is no reasonable expectation of success.

As stated above, the Specification provides that the "contrasting agent [is] incorporated in the matrix of the sponge. By 'incorporated' is meant that the contrasting agent is substantially dispersed throughout the sponge so that the contrasting material is not simply found on the periphery of the sponge." (Specification, page 7, lines 26-29 and page 8, line 1). Thus, the contrasting material is substantially dispersed throughout the sponge such that the pledget already contains the contrasting material prior to hydration as claimed in claim 16.

Neither Chuang nor Rosenblatt teach or suggest an "absorbable sponge material [which] includes a contrasting agent" as provided for in claim 16. In fact, upon closer reading of Rosenblatt, Rosenblatt teaches away from the claimed invention. Rosenblatt teaches "a medical sponge which is . . . capable of being homogeneously radiopaque **without** incorporating a leachable X-ray opaque material into the sponge." (Col. 3, lines 55-60). Rosenblatt discloses a sponge "having uniform pore geometry and pore size distribution" in order to achieve its radiopaqueness. (See, claim 1, col. 14, lines 10-12; Col. 10, lines 14-16). Thus, Rosenblatt teaches away from the claimed invention since it does not teach incorporating a contrasting agent into the sponge. Thus, there is no reasonable expectation of success.

B. The prior art references when combined do not teach or suggest all the claim limitations

As stated above, neither Chuang nor Rosenblatt teach or suggest an "absorbable sponge material includes a contrasting agent" as provided for in claim 16. Rather, Chuang teaches the method of adding or injecting liquid contrast medium separately to the Gelfoam. Rosenblatt does

not teach the use of a contrasting agent. Thus, the prior art references do not teach or suggest all the claim limitations.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance. It is respectfully requested that this rejection be withdrawn.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,
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